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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,047	12/06/2001	Theodora Ross	UM-06692	6232

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,047	ROSS ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-83 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, as specifically drawn to an antibody that specifically binds to HIP1 but not specifically bind to the normal epithelium or prostate or colon, classified in class 530, subclass 387.1.

II. Claims 9-18, 23-29, and 34-38, as specifically drawn to a method of detecting cancer and characterizing tissues by detecting the presence or absence of HIP1 mRNA in a sample, classified in class 436, subclass 64.

III. Claims 9-15, 19-26, and 30-38, as specifically drawn to a method of detecting cancer and characterizing tissues by detecting the presence or absence of HIP1 polypeptide in a sample, classified in class 436, subclass 64.

IV. Claims 39-42 and 44, as specifically drawn to a kit for characterizing cancer in a subject comprising an antibody that specifically binds HIP1 polypeptide, classified in class 435, subclass 810.

V. Claims 39 and 43-44, as specifically drawn to a kit for characterizing cancer in a subject comprising a nucleic acid probe that specifically binds to a HIP1 mRNA, classified in class 435, subclass 810.

VI. Claims 45-49 and 51-56, as specifically drawn to a method of screening compounds comprising detecting a change in HIP1 mRNA in a sample, classified in class 435, subclass 6; class 436, subclass 5.

VII. Claims 45-48, 50, and 53-56, as specifically drawn to a method of screening compounds comprising detecting the change in HIP1 polypeptide, classified in class 435, subclass 4.

VIII. Claims 57-67, as specifically drawn to a method of screening compounds by detecting a decrease in cells expressing wild type HIP1 relative to a second sample, classified in class 435, subclass 4.

IX. Claims 68-69 and 74, as specifically drawn to a nucleic acid and composition comprising a nucleic acid set forth in SEQ ID NO: 3, classified in class 536, subclass 23.1.

X. Claims 70-73, as specifically drawn to a composition comprising a polypeptide set forth in SEQ ID NO: 4, classified in class 530, subclass 350.

XI. Claims 75-79, as specifically drawn to a non-human transgenic mouse lacking a functional HIP1 gene, classified in class 800, subclass 18.

XII. Claims 80-83, as specifically drawn to a composition comprising a phosphoinositide mimetic which binds to wild type HP1 but not a HIP1 ENTH deletion mutant, classified in class 514, subclass 23.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I, IV-V, and IX-XII represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. For example, Group I is drawn specifically to an antibody that specifically binds to HIP1, whereas Group XI is specifically drawn to a non-human transgenic animal. Furthermore, Group IV is drawn specifically to a kit for

characterizing cancer in a subject, where as Group XII is drawn to a composition comprising a phosphoinositide mimetic.

The invention of Groups II-III, VI-VIII are materially distinct methods of which differ at least in objectives, method steps, reagents and/or dosage and/or schedules used, response variables, and criteria for success. For example, Group II is drawn to a method of detecting cancer and characterizing tissues by detecting the presence or absence of HIP1 mRNA, whereas Group III is also drawn to detecting cancer and characterizing tissues but detects the presence or absence of HIP1 polypeptide.

The inventions of Groups I, XII and the method of Group VII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of screening compounds for a change in HIP1 expression can be practiced with another materially different product such as a small organic molecule.

The inventions Group IX and method of Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group IX can be used in a materially different process such as for the production of a polypeptide.

The protein of Group X is related to the antibody of Group I by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used in other, materially different processes from the production of antibody such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein if

it is a receptor. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions.

The inventions Groups IV, V and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the kit of Group V, the kit of Group IV, and the transgenic mouse of Group XI do not require each other for their practice; have separate utilities, such as use of the Group V a kit for characterizing cancer comprises an antibody versus the kit of Group IV comprising a nucleic acid probe versus the transgenic mouse lacking a functional HIP1 gene; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35

U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER